

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of implementing prevention of Central Line Associated Blood Stream infection bundle on the incidence of this infection in patients admitted to intensive care units

Protocol summary

Study aim

Identification of the effect of implementing a care bundle for prevention of blood infection related to central venous catheter on the incidence of this infection in patients admitted to intensive care units of Namazi Hospital- Shiraz

Design

Intervention - Randomized controlled clinical trial

Settings and conduct

This research will be performed in two intensive care units of Namazi Hospital. One of them will be randomly selected by tossing a coin as the intervention ward and the other will be selected as the control ward. These wards are similar in terms of type of patients and medical team and disciplines. In the control group, care of central venous catheter will be performed according to the hospital protocol. In the intervention group, beside following the hospital protocol, a care bundle including the use of transparent dressing and bionector connector, and early catheter removal in absence of clinical indication will be used.

Participants/Inclusion and exclusion criteria

*Inclusion criteria -Admitted in general and central ICUs of Namazi hospital -completion of the informed consent - having central venous catheter -having age18-80 years
*exclusion criteria -Catheter removal less than 48 hours after placement -Occurrence of symptoms of local infection or bloodstream infection associated with central venous catheter less than 48 hours after catheter placement -Death of the patient

Intervention groups

In the intervention group, care of central venous catheter in patients who have the inclusion criteria, beside the performance of hospital protocols, will be done using bionector, transparent dressing, and supervising early catheter removal in absence of clinical indication. In the control group, care of the selected patients, will be

performed according to hospital protocols.

Main outcome variables

Incidence of blood infection associated with central venous catheter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160525028060N4**

Registration date: **2022-08-02, 1401/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-02, 1401/05/11**

Update count: **0**

Registration date

2022-08-02, 1401/05/11

Registrant information

Name

Fereshteh Dehghanrad

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3235 4285

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing prevention of Central Line Associated Blood Stream infection bundle on the incidence of this infection in patients admitted to intensive care units

Public title

The effect of implementing prevention of Central Line Associated Blood Stream infection bundle on the incidence of this infection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Admitted in general and central ICUs of Namazi hospital
Completion OF the informed consent form
Having central venous catheter having age between 18-80years

Exclusion criteria:

Catheter removal less than 48 hours after placement
Symptoms of local infection or bloodstream infection associated with central venous catheter less than 48 hours after catheter placement
Death of the patient
Transferring the patient from the intervention and control wards to other wards

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **340**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with flipping the coin method in which one of two wards is selected as intervention group ward and the other is selected as control group ward according to be head or tails

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand BLVD,shiraz

City

Shiraz

Province

Fars

Postal code

123456

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.036

Health conditions studied**1****Description of health condition studied**

Blood infection associated with central venous catheter

ICD-10 code

B99

ICD-10 code description

other infectious disease

Primary outcomes**1****Description**

Incidence of blood infection associated with central venous catheter

Timepoint

During the intervention

Method of measurement

Blood culture

Secondary outcomes**1****Description**

the length of ICU stay

Timepoint

until the end of time of Intensive Care Unit stay

Method of measurement

time: day

Intervention groups**1****Description**

Intervention group: Patients in intervention group, in

addition to receive hospital protocol about central catheter care, receive the prevention of catheter related blood stream infection care bundle including: the use of bionector connector for insuring closed system, use of transparent dressing for covering the insertion site, and supervising early catheter removal in absence of clinical indication.

Category

Prevention

2**Description**

Control group: Patients in control group, receive care of central venous catheter according to the hospital protocol.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi hospital

Full name of responsible person

Dr Ahmad Hosseinzadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fereshteh Dehghanrad

Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available